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Noninferiority of biocompatible solutions in peritoneal dialysis cannot be maintained

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To the Editor: We read with interest the results of the clinical trial comparing biocompatible with standard solutions in peritoneal dialysis.[1] We believe that the authors' claim of noninferiority of biocompatible solutions compared to standard solutions is not supported by their data. If the difference in the mean of urea and creatinine clearance, ΔnCrCl, between the two groups was −6.5 l per week and its standard deviation was 6 l per week then its 95% confidence interval was −18.42 to 5.42 l per week and the corresponding figures in ml/min units were −1.87 ml/min (−1.83 to 0.54 ml/min).[2] As a result, a noninferiority hypothesis set on the assumption that the difference is less than 1 ml/min cannot be maintained as the lower limit of the 95% confidence interval, −1.83 ml/min, is far lower than 1 ml/min.

We do not understand how the probabilities of actual differences in ΔnCrCl or ΔUvol being greater than particular figures were calculated, especially ΔnCrCl, highly inconsistent with its confidence interval. Standard, frequentist, statistics can only calculate the probability that a test statistic would be as extreme as or more extreme than observed if the null hypotheses were true, the *P*-value. Alternatively, Bayesian statistics can provide those probabilities,[3] but no mention was made of it in the article.

Further studies with larger sample sizes are needed also to assess whether biocompatible solutions are indeed noninferior to standard solutions.

1. Fan SL, Pile T, Punzalan S *et al.* Randomized controlled study of biocompatible peritoneal dialysis solutions: effect on residual renal function. *Kidney Int* 2008; **73**: 200–206.
2. Armitage P, Berry G. *Statistical Methods in Medical Research*, 2nd edn, Blackwell Scientific Publications: Oxford, 1987: 108.
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Response to noninferiority of biocompatible solutions in peritoneal dialysis cannot be maintained

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I thank Dr Garcia-Lopez for asking me to clarify the statistics I used in my article.

Existing publications (including his own[1]) suggest that biocompatible peritoneal dialysis solutions would be superior than standard. With this in mind, we wished to determine if patients using biocompatible peritoneal dialysis solutions would have a smaller decrement in nCrCl. We decided to use a predefined cutoff that we felt was clinically relevant, of 1 ml/min; that is inferiority of standard solutions would be proven if $\Delta nCrCl_{biocom}$–$\Delta nCrCl_{stand} > +1$ ml/min. Dr Garcia Lopez has correctly calculated that the 95% confidence interval for $\Delta nCrCl_{biocom}$–$\Delta nCrCl_{stand}$ was −1.83 to +0.54 ml/min. As +1 ml/min falls outside this range, we could not demonstrate that standard solutions were inferior (that is, we demonstrated noninferiority).

The difference between the expected ΔnCrCl (+1 ml/min) and the observed ΔnCrCl (−0.64 ml/min) was 1.64 ml/min. The standard error was 0.6, therefore the observed ΔnCrCl was > 2.7 s.e. outside the expected ΔnCrCl. The probability of randomly selecting a group of normally distributed patients who lie > 2.7 s.e. from the expected mean is ~0.003.

We claimed that standard solutions are not inferior to biocompatible (with regard to preserving residual renal function in unselected incident peritoneal dialysis patients). I therefore strongly refute any suggestions that our claims are not supported by data.

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The long forgotten salt factor

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To the Editor: Davenport *et al.*[1] were able to write an article on hypertension control in dialysis patients of several thousand words in length without mentioning the word salt. This is curious given the wide publicity that an article by Cook *et al.*[2] on the highly significant benefit obtained with 5–6 g salt intake per day in reducing cardiovascular morbidity and mortality in a 'prehypertensive healthy population'. The study, over a 10-year period, was randomized and controlled, and involved several thousand individuals.[2] This latter